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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,712	EILAT, ERAN	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,29,40,43,45,54 and 64-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24, 29, 40, 43, 45, 54, 64-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims **24, 29, 40, 43, 45, 54, 64-81** are pending and under examination.

Claim Objections

Claims 54, 65-67, 75 and 77 as written include the phrase "is selected from". Proper Markush language is “selected from the group consisting of”. The examiner suggests rewording the claim to include the Markush language. Note: MPEP 2111.03.

In claim 76, line 4, a comma “,” is missing between two species of kanamycin and ciprofloxacin.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **76, 78-81** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses active agents, such as antibiotics, steroids, antifungals, anesthetics, such as neomycin, ciprofloxacin, betamethasone, fluconazole, benzocaine, etc, which meet the written description and enablement provisions of 35

USC 112, first paragraph. However, claims 76, 78-81 are directed to encompass derivatives thereof, which only correspond in some undefined way to specifically instantly disclosed actives. Only the specifically disclosed active agents meet the written description provision of 35 USC § 112, first paragraph. The broad genus however does not, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides no guidance as to determine compounds which fulfill this description especially since derivatives vary. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed active agents, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, regardless of the complexity or simplicity of the method of preparation or isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant

> complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above active agents defined, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Tamarkin et al (US 20050031547).

Tamarkin et al teach a stable oleaginous cosmetic or therapeutic foam compositions containing certain active agent, having unique therapeutic properties and

methods of treatment using such compositions (see abstract). The foam formulations are intended for dermal and mucosal delivery of pharmaceutical and cosmetics (see [0011] and [0012]).

Tamarkin et al disclose that the composition includes:

a. at least one solvent selected from a hydrophobic solvent, a co-solvent, and mixtures thereof, wherein the solvent is present at a concentration of about 70% to about 96.5% by weight of the total composition (see [0014] and [0058]);

b. a non-ionic surface-active agent at a concentration of about 0.1% to less than about 10% by weight of the total composition (see [0015] and [0059]);

c. at least one gelling agent at a concentration of about 0.1% to about 5% by weight of the total composition (see [0016] and [0060]);

d. at least one active agent in a therapeutically effective concentration (see [0017] and [0061]); and

e. at least one liquefied or compressed gas propellant, at a concentration of about 3% to about 25% by weight of the total composition (see [0018] and [0062]).

Tamarkin et al also disclose that water and optional ingredients are added to complete the total weight to 100% (see [0019]). The oleaginous composition includes water at a concentration less than about 30%, preferably less than about 20%, more preferably less than about 10% by weight (see [0020]). The said oleaginous composition further includes a foam adjuvant (see [0021]). The oleaginous composition forms an emulsion (see [0022]). Suitable co-solvents, surface-active agents and gelling agents are disclosed (see [0095] to [0111]; [0116] to [0128] and [0129] to [0134]).

Tamarkin et al teach that the active agent may be a single agent or a combination of active agents. Suitable actives include analgesics, antibacterials, antifungals, antivirals, antiinflammatories, anesthetics, steroids, etc. Antibiotics such as erythromycin and **zinc** salts are also disclosed (see [0147] to [0220] and [0233]).

Tamarkin et al further disclose that the **foam therapeutic** product is adapted for storage in an aerosol container having **metered dose** valve associated therewith for dispensing an accurate dose of the drug in the form of a foam (see [0305] to [0307]). The said oleaginous compositions are useful for the treatment and prevention of disorders and diseases of body cavities such as **ear canal** (see [0312] and [0318]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40, 43, 45, 54, 64-81 rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20050031547).

Tamarkin et al teach a stable oleaginous cosmetic or **therapeutic foam** compositions containing certain active agent, having unique therapeutic properties and methods of treatment using such compositions (see abstract). The foam formulations are intended for dermal and mucosal delivery of pharmaceutical and cosmetics (see [0011] and [0012]).

Tamarkin et al disclose that the composition includes:

a. at least one solvent selected from a hydrophobic solvent, a co-solvent, and mixtures thereof, wherein the solvent is present at a concentration of about 70% to about 96.5% by weight of the total composition (see [0014] and [0058]);

b. a non-ionic surface-active agent at a concentration of about 0.1% to less than about 10% by weight of the total composition (see [0015] and [0059]);

c. at least one gelling agent at a concentration of about 0.1% to about 5% by weight of the total composition (see [0016] and [0060]);

d. at least one active agent in a therapeutically effective concentration (see [0017] and [0061]); and

e. at least one liquefied or compressed gas propellant, at a concentration of about 3% to about 25% by weight of the total composition (see [0018] and [0062]).

Tamarkin et al also disclose that water and optional ingredients are added to complete the total weight to 100% (see [0019]). The oleaginous composition includes water at a concentration less than about 30%, preferably less than about 20%, more preferably less than about 10% by weight (see [0020]). The said oleaginous composition further includes a foam adjuvant (see [0021]). The oleaginous composition forms an emulsion (see [0022]). Suitable co-solvents, surface-active agents and gelling agents are disclosed (see [0095] to [0111]; [0116] to [0128] and [0129] to [0134]).

Tamarkin et al teach that the active agent may be a single agent or a combination of active agents. Suitable actives include analgesics, antibacterials, antifungals, antivirals, antiinflammatories, anesthetics, steroids, etc. Antibiotics such as erythromycin and **zinc** salts are also disclosed (see [0147] to [0220] and [0233]).

Tamarkin et al further disclose that the foam therapeutic product is adapted for storage in an aerosol container having metered dose valve associated therewith for dispensing an accurate dose of the drug in the form of a foam (see [0305] to [0307]).

The said oleaginous compositions are useful for the treatment and prevention of disorders and diseases of body cavities such as ear canal (see [0312] and [0318]).

Tamarkin et al do not anticipate the claims because they lack specific disclosure on treating a disorder of the ear and a device comprising an extension extending from the container. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Tamarkin et al to arrive at the claimed invention, because Tamarkin et al disclose a foam formulation, comprising an active agent and foam adjuvants, intended for use in a body cavity such as ear for treating disorders, wherein the foam is delivered by a metered dose device comprising a canister and a valve. It would have been obvious to one of ordinary skill in the art that to deliver the foam into ear canal an extension extending from the container would be beneficial. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

Furthermore, it has been held that "It is well-established that consideration of a reference is not limited to the **preferred embodiments** or **working examples**, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the submitted knowledge in the art, to a person of ordinary skill in the art. In re Boe, 355, F.2d 961, 148 USPQ 510, 510 (CCPA 1966).

Claims 24, 29, 40, 43, 45, 54, 64-81 rejected under 35 U.S.C. 103(a) as being unpatentable over Abram (US 6,730,288) in view of Purwar et al (5,843,930).

Abram teach a pharmaceutical aerosol foam composition including an effective amount of a pharmaceutically active ingredient, an occlusive agent, an aqueous solvent, an organic cosolvent, the pharmaceutically active ingredient being insoluble in both water and occlusive agent (se abstract and col. 1, lines 43-59).

It is disclosed that various aerosol and non-aerosol quick breaking and slow breaking foams for the topical delivery of pharmaceutical active ingredients are known in the prior art. In particular, the foam composition is an aqueous emulsion system. The foam composition upon actuation produces a stabilised, homogeneous, expandable foam which breaks easily with shear. A composition of this type is often referred to as an aerosol foam or "mousse" (see column 1, lines 4-12).

Abram discloses that suitable active agents include analgesics, antifungals, antibacterials, anesthetics, antivirals, anti-inflammatories, steroids, etc (see paragraph bridging columns 1 and 2). The pharmaceutical aerosol foam composition may include an effective amount of a propellant such as hydrocarbons, HFCs nitrogen, etc. The propellant may be introduced into the mousse composition at the time of filling utilising for example a standard aerosol dispenser, e.g. a spray can arrangement (see col. 2, lines 23-35). The mousse formulations may contain an occlusive agent selected from mineral oils and greases, animal fats and greases, vegetable fats and greases, etc. preferred occlusive agent is petrolatum. The formulation may contain an effective

amount of an emulsifier and/or surfactant. The emulsifier or surfactant may be a non-ionic, anionic or cationic surfactant such as fatty alcohols, fatty acids and fatty acid salts thereof. Surfactant may be a mixture of sorbitan monostearate and polysorbate 60. The emulsifier is present in a stabilizing amount (see col. 2, line 36 to col. 3, line 45).

Abram further teaches that an aqueous solvent may be present in an amount of from 25% to 95% by weight based on the total weight of the composition (see col. 3, line 46 to col. 4, line 12).

Abram teaches foam formulations comprising a foam base, an active agent and adjuvants, but lacks specific disclosure on introducing the mixture into a dispensing device adapted for the dispensing the composition to the external auditory meatus. This deficiency is cured by Purwar et al.

Purwar et al teach a method of treating otitis by introducing an antibacterially-effective amount of a composition comprising a non-toxic, topical, otic pharmaceutical composition comprising, ciprofloxacin, a non-ionic viscosity augmenter, preservative, water, hydrocortisone, lecithin and a polysorbate 20-80 (see abstract and Summary). The formulations also comprise acetic acid in an amount sufficient to buffer the composition (col. 2, lines 65-68 and col. 4, lines 59-68).

An example of a formulation for delivering to the ear comprising ciprofloxacin HCL, water, glycerin, polysorbate 20 and other adjuvants is disclosed in Table 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Abram and Purwar et al with a reasonable expectation of successfully preparing a foam formulation for the easy delivery of an active agent topically. While Abram does not specifically teach administration of the foam formulation comprising the active agent to the ear canal, it would have been obvious to one of ordinary skill in the art to deduce such from the combined teachings because Abram teaches foam formulations comprising an active agent delivered topically and Purwar discloses topical formulations comprising an active agent delivered to the ear canal. It would have been obvious because the combination of the two references would have lead one of ordinary skill in the art to the claimed invention. It has been held that "when an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."

KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

Although neither references teach a dispensing device containing an extension, Abram teaches a spray device for delivering its foam formulations. Thus, it would have been obvious to one of ordinary skill in the art to employ a suitable delivery device or to modify the device to adjust for ear canal delivery.

Claims 24, 40, 43, 54, 64-68, 71, 73-76 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (US 4,305,936) in view of Purwar et al (5,843,930).

Klein teach topical or local application comprising at least one corticosteroid, from about 1 to 4% by weight of solubilization agents consisting essentially of a combination of at least one glyceryl ester of a fatty acid of 6 to 22 carbon atoms and a betaine surfactant, from about 10% to 50% by weight of a composition of an alkanol cosolvent, and from about 20% to 50% water (see abstract and col. 2, lines 13-27). It is disclosed that local application means use in body cavities such as vaginal, nasal, etc (col. 1, lines 48-50). Klein also discloses a new topical or local preparation which can produce a foam when packaged either in the form of an aerosol or a non-aerosol foam-forming closure system (see col. 2, lines 7-10). Klein also disclose that propellants such as liquefied gases, nitrogen, propane, etc are employed in preparing aerosols (see col. 6, lines 6-11). Klein lacks disclosure on introducing the mixture into a dispensing device

adapted for the dispensing the composition to the external auditory meatus. This deficiency is cured by Purwar et al.

Purwar et al teach a method of treating otitis by introducing an antibacterially-effective amount of a composition comprising a non-toxic, topical, otic pharmaceutical composition comprising, ciprofloxacin, a non-ionic viscosity augmenter, preservative, water, hydrocortisone, lecithin and a polysorbate 20-80 (see abstract and Summary). The formulations also comprise acetic acid in an amount sufficient to buffer the composition (col. 2, lines 65-68 and col. 4, lines 59-68).

An example of a formulation for delivering to the ear comprising ciprofloxacin HCL, water, glycerin, polysorbate 20 and other adjuvants is disclosed in Table 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Klein and Purwar et al with a reasonable expectation of successfully preparing a foam formulation for the easy delivery of an active agent topically. While Klein does not specifically teach administration of the foam formulation comprising the active agent to the ear canal, it would have been obvious to one of ordinary skill in the art to deduce such from the combined teachings because Klein teaches foam formulations comprising an active agent delivered topically and locally to body cavities, and Purwar discloses topical formulations comprising an active agent delivered to the ear canal. It would have been obvious because the combination of the two references would have lead one of ordinary

skill in the art to the claimed invention. It has been held that "when an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

Although neither references teach a dispensing device containing an extension, Abram teaches a spray device for delivering its foam formulations. Thus, it would have been obvious to one of ordinary skill in the art to employ a suitable delivery device or to modify the device to adjust for ear canal delivery.

All pending claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616